Remarks

In the Office Action mailed January 6, 2004, the claims were divided into 16 groups.

Group I Claims 1-3, 19, 29-31, 35-36, 38-39, (in part) and claim 4, drawn to a method of administering to a patient a compound that inhibits the effect of aldosterone.

Group II Claims 1-2, 5, 6, 19, 29-31, 35-36, 38-39, 41 (in part) and claim 6, drawn to a method of administering to a patient a chymase inhibitor.

Group III Claims 1-2, 7, 19, 29-31, 35-36, 38-39, 41 (in part) and claim 8, drawn to a method of administering to a patient a cathepsin inhibitor.

Group IV Claims 1-2, 9, 11, 13, 15, 19, 23, 29-31, 35-36, 38-39, 41 (in part) and claims 10, 12, 16 and 24, drawn to a method of administering to a patient a receptor blocker.

Group V Claims 1-2, 17, 19, 29-31, 35-36, 38-39, 41 (in part) and claim 18, drawn to a method of administering to a patient a ganglion blocking agent.

Group VI Claims 1-2, 19, 21, 29-31, 35-36, 38-39, 41 (in part) and claim 20, drawn to a method of administering to a patient an opiate.

Group VII Claims 1-2, 19, 29-31, 35-36, 38-39, 41 (in part) and claim 22, drawn to a method of administering to a patient a compound that inhibits the effect of scopolamine.

Group VIII Claims 1-2, 19, 25, 29-31, 35-36, 38-39, 41 (in part) and claim 26, drawn to a method of administering to a patient a xanthine oxidase inhibitor.

Group IX Claims 1-2, 19, 29-31, 35-36, 38-39, 41 (in part) and claim 27, drawn to a method of administering to a patient an erythropoietin.

Group X Claims 1, 19, 29-31, 35-36, 41 (in part) and claim 14, drawn to a method of administering to a patient a receptor agonist.

Group XI Claims 38 and 39 (in part), drawn to a method of administering to a patient a digitalis alkaloid.

Group XII Claims 38 and 39 (in part), drawn to a method of administering to a patient a growth hormone.

Group XIII Claims 38 and 39 (in part), drawn to a method of administering to a patient an insulin like growth factor.

Group XIV Claims 38 and 39 (in part), drawn to a method of administering to a patient an endothelin antagonist.

Group XV Claims 38 and 39 (in part), drawn to a method of administering to a patient a TNF antagonist.

Group XVI Claims 28, 37, 40 and 46-47, drawn to a method of electrically stimulating a patient's muscles.

Applicants provisionally elect Group I Claims 1-3, 19, 29-31, 35-36, 38-39, (in part) and claim 4, drawn to a method of administering to a patient a compound that inhibits the effect of aldosterone with traverse.

The Restriction Requirement is Improper.

The Examiner has applied PCT rules for Unity of Invention because this application is a 371 of PCT/GB99/03302. PCT Rule 13.2 deals with the requirement of unity of invention and defines the method for determining whether the requirement is satisfied. "Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding "special technical features".

The independent claims in the present application are sufficiently linked as to form a single general inventive concept. This inventive concept finds expression in common technical features which define the inventive contribution that the claims invention makes over the prior art. Specifically to treat weight loss by administering an inhibitor of sympathetic nervous system activity. The common features linking the independent claims presently in the application are not known in the art.

At most, the claims should have been divided into the following groups along with an election of species for the compound to reduce sympathetic nervous system activity.

Group I: claims 1-27, 29-31, 35 and 36 drawn to a method of treating weight loss by administration of an effective amount of an agent which reduces sympathetic nervous system activity.

Group II: claims 28, 37, 46 and 47 drawn to a method of treating weight loss by electrically stimulating the patient's muscles.

Group III: claims 38-40 drawn to a method of enhancing exercise performance.

Group IV: claim 41 drawn to a method of treating weight loss associated with a cardiovascular disorder.

The Claims meet the Unity of Invention Standards for Markush Practice

PCT Rule 13.2 also governs so called Markush practice. When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of similar nature where the following criteria are fulfilled:

(A) all alternatives have a common property or activity, and

(B)(1) a common structure is present,

(B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

In the present application, the claims have the common property/ activity of decreasing sympathetic nervous system activity and are all recognized as being sympathetic nervous system blockers. These are known compounds with art recognized activities and classification.

Division of Single Claims into Multiple Inventions is Improper

It is improper to divide a single claim such as claim 1 into a plurality of inventions as the Examiner has done. Proper practice would be to require an election of species for search purposes. It is understood that once a species is determined to be free of prior art, the remaining species will also be searched.

The proper restriction in the instant application would be to divide the claims based on the method of treatment as described above and require and election of species for the compound to be administered.

Claims 1-27, 29-31, 35 and 36 all clearly define essential characteristics of the single embodiment of the invention that being *a method of treating weight loss by administration of an effective amount of an agent which reduces sympathetic nervous system activity.* The examiner has divided the generic claims into different groups based on description in the specification of what molecules can be used, *even in the complete absence of any such limitations in the claims!*

There is **no limitation** in these claims to specific compounds to inhibit sympathetic nervous system activity. Clearly, **the examiner is trying to impose limitations NOT PRESENT IN THE CLAIMS through the vehicle of a restriction requirement.**

It is stated in the MPEP that, "where the claims of an application define the same essential characteristics of a single disclosed embodiment of an invention, restriction therbetween should never be required. This is because the claims are but different definitions of the same disclosed subject matter, varying in breadth or scope of definition." (MPEP 806.03)

The case has already been pending for three years. In that time the Examiner has issued two restriction requirements and a letter requesting clarification. A first action on the merits of this application has not yet been issued. The present restriction requirement is further delaying prosecution of this application. Applicants request rejoinder of the claims and examination on the merits.

U.S.S.N. 09/807,558
Filed: July 17, 2001
AMENDMENT AND RESPONSE TO OFFICE ACTION

Examination and allowance of all claims 1-47 is earnestly solicited. Applicants intend to petition for review of this restriction requirement, should it be maintained.

Respectfully submitted,

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Date: February 5, 2004

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Certificate of Facsimile Transmission

I hereby certify that this Amendment and Response to Office Action, and any documents referred to as attached therein are being facsimile transmitted on this date, February 5, 2004, to the Commissioner for Patents, U.S. Patent and Trademark Office, Washington, DC 20231.

Jenny Vicente

Date: February 5, 2004

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078230/00027